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May 26, 2006

Mr. Stephen Johnson, Administrator U.S. Environmental Protection Agency Ariel Rios Building, 1101 -A 1200 Pennsylvania Ave., N.W. Washington, DC 20460 2766121/31 ATIO 50

Subject: Public comments on the HPV Test Plan for the Chlorinated pyridines category

Dear Administrator Johnson:

The following comments on Dow's test plan for the chemical category, Chlorinated pyridines, are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The Dow Chemical Company submitted its test plan on Dec. 21, 2005, for the chemical category, Chlorinated pyridines, which consists of six chemicals: 2 3 4 5,6-pentachloropyridine (CAS No. 2 176-62-7), 3,4,5,6-tetrachloro-2-pyridine carbonitrile (CAS No. 17824-83-8), 3,6-dichloro-2-trichloromethylpyridine (CAS No. 18 17-13-6), 2-chloro-5-trichloromethylpyridine (CAS No. 2402-79-1), chloropyridine derivatives (CAS No. 68412-40-8), and methyl chloropyridine derivatives (CAS No. 70024-85-O), as well as one supporting chemical, 2,3,5,6-tetrachloropyridine (CAS No. 2402-79-1). We are pleased to see that Dow has now grouped these similar chemicals into a single category that supersedes previous HPV test plans submitted for each individual chemical. This is a scientifically valid approach for hazard assessment and also serves to reduce the number of animals killed in the HPV program. We support this type of analysis and concur with Dow that no additional testing is required.

Dow has submitted measured data for all SIDS endpoints for 2,3,4,5,6-pentachloropyridine, as well as for the supporting chemical, 2,3,5,6-tetrachloropyridine. For the remaining chemicals, a combination of existing data and modeled data were used in a weight-of-evidence approach to bridge data gaps. We appreciate Dow's efforts to conduct thoughtful toxicology in order to avoid additional animal testing.

We note that there are some differences in the **physicochemical** properties and toxicity among the chemicals in this category. However, all category members are used in the production of chlorinated pesticides and are therefore, already regulated under FIFRA and indeed, are subject to numerous animal tests to determine health hazards. Existing data on subchronic toxicity shows similar **NOAELs** (lo-100 **mg/kg/day**) and a similar

profile of target organs (kidney and liver) for the various chemicals. Moreover, genotoxicity studies consistently produced negative results for the category members tested. Developmental studies conducted with 2,3,4,5,6-pentachloropyridine show a NOEL of 10 mg/kg/day for maternal toxicity with a clear NOEL established at 50 mg/kg/day for developmental toxicity. Although a reduction in fetal weight was reported, these effects were seen only at doses there were also maternally toxic. In another study, a reproductive/developmental screen (GLP) conducted with 2,3,5,6-tetrachloropyridine, no effects on offspring were reported even at maternally toxic levels. These data, when considered together, suggest additional animal studies will not add to our knowledge of the toxicity of chlorinated pyridines and will only serve as a "check-the-box" exercise.

Previous comments submitted by EPA and ED on the individual chemicals raised concerns about the toxicity pattern of less chlorinated to completely chlorinated pyridines. However, existing data for 2,3,5,6-tetrachloropyridine, the least chlorinated member of this category, shows similar toxicity to all other members for health effects, even as the level of chlorination increases. We hope Dow can provide additional information to further support the argument that slight differences in physicochemical properties of the category members do not appear to be toxicologically relevant to health effects.

Finally, all chemicals in the category, except 2,3,4,5,6-pentachloropyridine, are described as site-limited intermediates. Although Dow does not characterize these chemicals as closed-system intermediates, the potential for exposure is extremely limited and some of these materials are incinerated, which may eliminate the need for repeated dose and reproductive toxicity testing in the HPV program. Moreover, adequate measures to protect workers from occupational exposure have already been established. We agree with Dow's proposal that no additional animal studies are needed to fulfill the SIDS data set for the chlorinated pyridines category. Thank you for your attention to these comments. I may be reached at 202-686-22 10, ext. 327, or via e-mail at meven@pcrm.org.

Sincerely,

Megha Even, M.S. Research Analyst

Chad B. Sandusky, Ph.D. Director of Toxicology and Research